STEVE W. BERMAN (*pro hac vice*)
steve@hbsslaw.com
HAGENS BERMAN SOBOL SHAPIRO LLP
1918 Eighth Avenue, Suite 3300
Seattle, WA 98101
Telephone: (206) 623-7292
Facsimile: (206) 623-0594
-and-
LEE M. GORDON (SBN 174168)
lee@hbsslaw.com
HAGENS BERMAN SOBOL SHAPIRO LLP
301 North Lake Avenue, Suite 203
Pasadena, CA 91101
Telephone: (213) 330-7150
Facsimile: (213) 330-7152

Counsel for Plaintiff
and the Proposed Class

UNITED STATES DISTRICT COURT

CENTAL DISTRICT OF CALIFORNIA

SOUTHERN DIVISION

JOSETTE RUHNKE, an individual, *et al.*; on behalf of herself and all others similarly situated,

Plaintiff,

vs.

SKINMEDICA, INC., a Delaware Corporation, and ALLERGAN, INC., a Delaware Corporation,

Defendants.

Case No. 8:14-cv-00420 DOC (JPRx)

CLASS ACTION

PLAINTIFF'S OPPOSITION TO DEFENDANTS' MOTION TO DISMISS FIRST AMENDED CLASS ACTION COMPLAINT UNDER FEDERAL RULE OF CIVIL PROCEDURE 12(B)(6)

Date: August 4, 2014
Time: 8:30 a.m.
Ctrm: 9D
Judge: Hon. David O. Carter

TABLE OF CONTENTS

Page

I. INTRODUCTION 1

II. FACTUAL BACKGROUND 3

A. The Parties 3

B. TNS® Products and the Growth Factor Mix Contained Therein 4

C. Defendants' Marketing and Sale of TNS® Products 5

D. Drug and Cosmetic Regulatory Requirements 6

E. Safety Concerns Associated with the TNS® Growth Factor Mix 7

F. Defendants' Failure to Disclose the True Regulatory and Safety Status of TNS® Products 9

G. Plaintiff's Claims in This Action 9

III. LEGAL STANDARDS 9

A. Motion to Dismiss Standards under Rules 8(a), 9(b), and 12(b)(6) 9

B. General Standards for the UCL, CLRA, FAL, and Civil Deceit 10

IV. ARGUMENT 12

A. Plaintiff Adequately Alleges that TNS® Products Qualify as "Drug" Products. 12

B. Plaintiff Sufficiently Alleges that the Omitted Facts about the Regulatory Status and Safety Status of TNS® Products Are True. 16

1. *TNS® Products are unapproved drugs being sold to consumers illegally.* 16

2. *Defendants failed to adequately determine that TNS® Products are safe, which Defendants were required to do before marketing and selling such products to consumers.* 16

3. *The TNS® growth factor mix raises genuine safety conerns.* 19

C. Plaintiff Adequately Alleges a Duty to Disclose and Scienter. 21

D. Plaintiff Adequately Alleges Her Claims Against Defendant Allergan as a Parent Company that Cross-Promotes the TNS® Products. 21

1. *The FAC sufficiently differentiates between SkinMedica and Allergan.* 21

2. *The FAC sufficiently alleges that Allergan holds out TNS® Products to be Allergan products.* 22

E. Plaintiff Sufficiently Pleads a Claim for Punitive Damages. 22

F. Plaintiff Has Standing to Seek Injunctive Relief. 23

V. CONCLUSION 25

TABLE OF AUTHORITIES

Page(s)

CASES

Ashcroft v. Iqbal,
556 U.S. 662, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009) 9, 10

Bates v. United Parcel Serv., Inc.,
511 F.3d 974 (9th Cir. 2007) 23

Bell Atl. Corp. v. Twombly,
550 U.S. 544, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007) 10

Brazil v. Dole Food Co.,
935 F. Supp. 2d 947 (N.D. Cal. 2013) 14

Cel–Tech Cmmc'ns, Inc. v. Los Angeles Cellular Tel. Co.,
20 Cal. 4th 163, 973 P.2d 527 (1999) 11

Colgan v. Leatherman Tool Grp., Inc.,
135 Cal. App. 4th 663, 38 Cal. Rptr. 3d 36 (2006) 11

Corral v. Carter's Inc.,
No. 1:13-CV-0262 AWI SKO, 2014 WL 197782 (E.D. Cal. Jan. 16, 2014) 20

Eckler v. Wal-Mart Stores, Inc.,
No. 12-CV-727-LAB-MDD, 2012 WL 5382218 (S.D. Cal. Nov. 1, 2012) 20

Estée Lauder, Inc. v. FDA,
727 F. Supp. 1 (D.D.C. 1989) 12

Falk v. General Motors Corp.,
496 F. Supp. 2d 1088 (N.D. Cal. 2007) 10

Fortyune v. American Multi–Cinema, Inc.,
No. CV 10–5551, 2002 WL 32985838 (C.D. Cal. Oct. 22, 2002) 25

FTC. v. Pantron I Corp.,
33 F.3d 1088 (9th Cir. 1994) 14, 15

Henderson v. Gruma Corp.,
No. CV 10-04173 AHM 24, 25

Koehler v. Litehouse, Inc.,
No. CV 12-04055 SI, 2012 WL 6217635 (N.D. Cal. Dec. 13, 2012) 24

Lujan v. Defenders of Wildlife,
504 U.S. 555, 112 S.Ct. 2130, 119 L.Ed. 2d 351 (1992) 23

Manzarek v. St. Paul Fire & Marine Ins. Co.,
519 F.3d 1025 (9th Cir. 2008) 10

National Council Against Health Fraud v. King Bio Pharm., Inc.,
107 Cal. App. 4th 1336 (2003) 17, 18

O'Shea v. Littleton,
414 U.S. 488, 94 S.Ct. 669, 38 L.Ed. 2d 674 (1974) 24

Otto v. Abbott Labs., Inc..,
No. CV 12-1411-SVW (DTB), 2013 U.S. Dist. Lexis 53287 (C.D. Cal. Mar. 15, 2013) 20

Park v. Welch Foods, Inc.,
No. 5:12-CV-06449-PSG, 2013 WL 5405318 (N.D. Cal. Sept. 26, 2013) 14

Pedinol Pharmacal, Inc. v. Rising Pharm., Inc.,
512 F. Supp. 2d 137 (E.D.N.Y. 2007) 15

Peel v. BrooksAmerica Mortg. Corp.,
788 F. Supp. 2d 1149 (C.D. Cal. 2011) 10

Swartz v. KPMG LLP,
476 F.3d 756 (9th Cir. 2007) 10, 21

United States v. An Article… "Line Away, Temp. Wrinkle Smoother, Coty",
284 F. Supp. 107 (D. Del. 1968) *aff'd*, 415 F.2d 369 (3d Cir. 1969) 15

United States v. An Article ... "Line Away" ...,
415 F.2d 369 (3d Cir. 1969) 13

United States v. An Article ... "Sudden Change",
409 F.2d 734 (2d Cir. 1969) 13

United States v. Hohensee,
243 F.2d 367 (3rd Cir.1957) (*cert. denied*, 353 U.S. 976, 77 S.Ct. 1058, 1 L.Ed. 2d 1136 (1957)) 12

United States v. Kasz Enters.,
855 F. Supp. 534, *amended*, 862 F. Supp. 717 (D.R.I. 1994) 14, 15

United States v. Livdahl,
459 F. Supp. 2d 1255 (S.D. Fla. 2005) 12

United States v. Storage Spaces Designated Nos. "8" & "49",
777 F.2d 1363 (9th Cir. 1985) 12

Vess v. Ciba-Geigy Corp. USA,
317 F.3d 1097 (9th Cir. 2003) 10

White v. Ultramar, Inc.,
21 Cal. 4th 563 (1999) 23

Williams v. Wells Fargo Bank N.A.,
No. 11-21233-CIV, 2011 WL 4901346 (S.D. Fla. Oct. 14, 2011) 21

STATUTES

21 C.F.R. § 314 ..... 6, 16

21 C.F.R. §§ 740.10 ..... 7, 17

21 U.S.C. § 321 ..... 1, 6, 12

21 U.S.C. § 331 6

21 U.S.C. § 352 7

21 U.S.C. § 355 ..... 6, 16, 17

21 U.S.C. § 362 7

Cal. Bus. & Prof. Code §§ 17200, *et seq.* 9, 10, 11

Cal. Bus. & Prof. Code § 17201 10

Cal. Bus. & Prof. Code § 17203 10

Cal. Bus. & Prof. Code §§ 17500, *et seq.* 9, 11

Cal. Bus. & Prof. Code § 17508 17
Cal. Civ. Code § 1709 ..... 9, 12, 23
Cal. Civ. Code § 1710 ..... 9, 12, 23
Cal. Civil Code §§ 1750, *et seq.* 9, 11
Cal. Civ. Code § 1770 11
Cal. Civ. Code § 1780 22
Cal. Civ. Code § 3294 ..... 2, 3, 4, 23
Cal. Health & Safety Code § 109875. 9
Cal. Health & Safety Code § 109925 7
Cal. Health & Safety Code § 110290 17
Cal. Health & Safety Code § 111330 7
Cal. Health & Safety Code § 111335 7
Cal. Health & Safety Code § 111550 ..... 7, 16
Cal. Health & Safety Code § 111560 ..... 7, 16
Cal. Health & Safety Code § 111730 17
Consumers Legal Remedies Act 9
FDCA ..... *passim*
Sherman FD&C ..... *passim*

OTHER AUTHORITIES

FDA Cosmetic Labeling Manual, 1991 WL 11250880 (FDA Oct. 1, 1991) 17
U.S. Food and Drug Administration, FDA 101: BIOLOGICAL PRODUCTS (2008) 4, 7, 13
Fed. R. Civ. P. 8 ..... 1, 9

Fed. R. Civ. P. 9 ..... 1, 10, 21

Fed. R. Civ. P. 12 9

I. INTRODUCTION

Defendants SkinMedica, Inc. and Allergan, Inc. market and sell a misbranded line of skin care "cosmeceuticals" called "TNS®" (short for "Tissue Nutrient Solutions"). TNS® products ("TNS® Products") contain a mix of *human growth factors* and other biological components that have been bioengineered from human foreskin tissue. By design, TNS® Products induce cell growth and stimulate other physiological effects on the skin. Not surprisingly, *these products qualify as "drug" products* under federal and state laws alike.

In her First Amended Class Action Complaint ("FAC"), Plaintiff Josette Ruhnke alleges that Defendants market and sell misbranded TNS® Products without FDA-approval, without conducting well-controlled safety studies (as required by law), and despite genuine safety concerns. The challenged conduct violates the federal Food, Drug, & Cosmetics Act ("FDCA") as well as the parallel provisions of California's Sherman Food, Drug, and Cosmetics Law ("Sherman FD&C"). It also constitutes unlawful, unfair, and deceptive conduct in violation of California's consumer protection statutes.

Defendants now move to dismiss the FAC on grounds that Plaintiff does not plead her claims sufficiently and plausibly under Rules 8(a) and 9(b). Defendants are incorrect. The FAC comports with applicable pleading standards and provides clear notice of the alleged misconduct. In particular, Defendants' arguments fail for the following reasons.

Plaintiff adequately alleges that TNS® Products qualify as "drug" products. Skin creams often qualify as cosmetics *and* drug products, and TNS® Products certainly fit the bill. A "drug" includes any article "intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(C). Based on Defendants' promotional materials and other relevant sources, the FAC amasses substantial support for the claim that TNS® – a proprietary growth factor mix – is intended to affect the structure or function of the skin. Indeed, the whole idea of using TNS® growth

factors in topical skin creams is to promote skin cell growth, slow the skin's aging process, increase the skin's thickness and elasticity, and otherwise affect the skin's structure or function. Therefore, Plaintiff sufficiently alleges that TNS® Products are drug products.

Plaintiff sufficiently alleges that the omitted facts about the regulatory and safety status of TNS® Products are true. According to the FAC: (i) TNS® Products are unapproved and misbranded drugs being marketed and sold illegally to consumers in the United States; (ii) Defendants have failed to adequately determine that TNS® Products are safe (as required by law); and (iii) TNS® Products pose genuine safety concerns. These allegations are supported, among other things, by Defendants mistaken view that TNS® Products are strictly cosmetics, Defendants' lack of any new drug application for TNS® Products, and public reports confirming that safety studies for such products are lacking. The FAC also pleads ample facts about the safety concerns posed by growth factors contained in TNS® (including cancer risks).

Plaintiff adequately alleges Defendants' duty to disclose and scienter. The FAC alleges that Defendants had a duty to disclose the true regulatory/safety status of TNS® Products. This duty arises from the FDCA and Sherman FD&C, Defendants' superior and exclusive knowledge of the true facts, and Defendants' concealment of such facts.

Plaintiff adequately alleges claims against Defendant Allergan for cross-promoting TNS® Products. In December 2012, Allergan acquired SkinMedica. TNS® Products are now cross-promoted both as SkinMedica and Allergan products. Given this, the FAC adequately alleges that Allergan is liable for the same unlawful sales as SkinMedica (from and after the date of acquisition).

Plaintiff adequately pleads her claim for punitive damages. Contrary to Defendants' Motion, Civil Code Section 3294(b) does not apply here because this is not an action by an *employee* against an *employer*. Thus, there is no need for Plaintiff to make allegations about Defendants' "officers, directors, or managing agents," and

Plaintiff otherwise alleges willful misbranding and concealment of the sort that readily supports punitive damages.

Plaintiff has standing to seek injunctive relief. Plaintiff purchased a misbranded TNS® Product. As set forth in the FAC, Defendants continue to market and sell misbranded TNS® Products. Injunctive relief is warranted in cases of this sort.

II. FACTUAL BACKGROUND

A. The Parties

Defendant SkinMedica, Inc. ("SkinMedica") is a pharmaceutical company headquartered in Carlsbad, California. (FAC ¶ 11.) Defendant Allergan, Inc. ("Allergan") is a health care company headquartered in Irvine, California. (FAC ¶ 12.) SkinMedica markets and sells TNS® Products. (FAC ¶ 2.) In or about December 2012, Allergan acquired SkinMedica along with the rights and responsibilities associated with the TNS® Product line. (FAC ¶ 12.) At present, TNS® Products are also promoted as Allergan products. (*Id.*)

Plaintiff Josette Ruhnke purchased one of the TNS® Products – TNS Essential Serum – through her doctor's office in California during the putative class period, for personal use. (FAC ¶ 9.) If she had known that TNS® Products are being sold illegally without prior regulatory approvals, or that safety for these products had not been adequately determined, or about the potential health risks associated with TNS®, then she would not have purchased a TNS® Product (or would have paid less for it). (FAC ¶¶ 7, 10.) As a result, she overpaid for TNS® Products and suffered economic damage just as thousands of other consumers did. (FAC ¶¶ 7, 10, 70, 73-77, 85.)

This is *not a personal injury case* and Plaintiff need not prove that TNS® causes cancer or other adverse reactions. This is a putative class action that seeks: (i) to address the *economic* injuries suffered by thousands of consumers who purchased expensive and misbranded TNS® Products, and (ii) to prevent future injuries from the ongoing marketing of misbranded drug products to consumers.

B. TNS® Products and the Growth Factor Mix Contained Therein

TNS® Products contain a proprietary mix of "human growth factors" and other biological ingredients under the TNS® brand name and the "NouriCel-MD®" trademark. (FAC ¶¶ 2-3.) This TNS growth factor mix was derived from human foreskin tissue. (FAC ¶ 3.) Growth factors are proteins intended to mobilize, stimulate, decrease or otherwise alter the production of cells in the body. (FAC ¶ 4.) For example, growth factors can promote cell division. (*Id.*) In regulating biological products, the FDA's center for Drug Evaluation and Research describes "growth factors" as "proteins that affect the growth of a cell."[1]

In 2007, SkinMedica's research leader for TNS®, RE Fitzpatrick, published an article (the "*Fitzpatrick article*") entitled "Endogenous Growth Factors in Cosmeceuticals." (Defs. Req. for Judicial Notice, June 3, 2014, ECF No. 21 ("RJN"), Ex. 2.)[2] According to SkinMedica's research leader: "Topical application of human growth factors in multiple clinical studies has been shown to reduce the signs and symptoms of skin aging, including [statistically] significant reduction in fine lines and wrinkles and increase in dermal collagen synthesis." (*Id.* at 350.) The SkinMedica research proclaims that the flagship TNS Recovery Complex reduces fine lines, wrinkles, and sun damage around the eyes, and increases collagen and epidermal thickness. (*Id.* at 353-54.) Moreover, according to the *Fitzpatrick article*, topical application of growth factors and cytokines affects the dermal matrix. (*Id.* at 356.)[3]

Plaintiff alleges that SkinMedica markets several TNS® Products, all of which contain substantially the same proprietary mix of growth factors and other proteins—

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[1] U.S. Food and Drug Administration, FDA 101: BIOLOGICAL PRODUCTS, at 2 (2008), *available at:* http://www.fda.gov/forconsumers/ consumerupdates/ucm048341.htm.

[2] The parties agree that the Court may take judicial notice of the articles attached to Defendants' RJN (i.e., Exs. 1 and 2).

[3] For instance, the author explains how topical application of growth factors can penetrate hair follicles, sweat glands, or compromised skin, and interact with cells in the epidermis (such as keratinocytes) to produce signaling cytokines that affect cells deeper in the dermis. (*Id.*) It can stimulate keratinocyte growth, which can amplify the original growth factor effects, produce other growth factors, and regenerate and remodel the dermal extracellular matrix. (*Id.*)

i.e., each TNS® Product contains the same growth factor mix in one concentration or another. (FAC ¶¶ 19-22.) Each TNS® Product is a topical skin care product that is developed, marketed, and sold by SkinMedica. (*Id.*) The labeling and packaging of each product omits the same material facts and Plaintiff alleges the same misbranding under the same laws for the same reasons with respect to each product. (FAC ¶ 22.)

C. Defendants' Marketing and Sale of TNS® Products

Defendants intend for their TNS® Products to have a physiological effect on the skin, i.e., Defendants promote the ability of these products to stimulate skin cell growth, slow the skin's aging process, reduce sun damage, increase collagen production, increase the skin's thickness, and regenerate and remodel the skin's structure. (*See, e.g.*, RJN, Ex. 2; FAC ¶¶ 40, 46.) As set forth in the FAC, the following additional facts show that Defendants intend for TNS® to affect the structure and/or function of the skin:

- SkinMedica's 2004 IPO states: "We are a specialty *pharmaceutical company* focused on developing, acquiring and commercializing products that treat dermatologic conditions and diseases and improve the appearance of skin" (¶23) (emphasis added);
- Defendants market TNS® Products as physician-dispensed "cosmeceuticals", and sell these products primarily through dermatologist offices (¶¶ 20, 23);
- Defendants promote TNS® *growth factors* as key ingredients in the TNS Product line (¶23);
- SkinMedica's Product Guide describes the TNS® line as vital to the anti-aging process and working with the skin's "natural cellular restructuring process" to "reduce the appearance of fine lines and wrinkles, diminish age spots, and improve skin texture and elasticity" (¶ 25, Fig. 1, ¶ 40; *see also* RJN, Ex. 2);
- In its Product Guide, SkinMedica advertises its growth factors as

proteins that "regulate cellular growth and the activity of skin cells" (¶ 25);

- In its Product Guide, SkinMedica advertises how a "*physiologically balanced*" mix of growth factors is needed in the skin "to maintain a healthy skin structure" (¶ 25, Fig. 1);
- In the Product Guide, SkinMedica also advertises that growth factors are proteins that "regulate cellular growth and the activity of skin cells" (*Id.*);
- The Product Guide further describes TNS®, a "Tissue Nutrient Solution," as "a combination of growth factors and other naturally occurring elements that are crucial to the regeneration of healthy skin" (*Id.*);
- The Product Guide also describes its flagship TNS® Product as the first and only "patented anti-aging treatment" using a combination of "growth factors clinically proven to improve" skin tone, texture, elasticity, etc. (¶ 26); and
- TNS® Products are designed to affect the skin's structure and function by inducing skin cell division and growth, and stimulating the formation of collagen and elastic fibres in the skin. (¶ 40.)

D. Drug and Cosmetic Regulatory Requirements

Under the FDCA, a "drug" includes "articles (other than food) intended to affect the structure or any function of the body of man." 21 U.S.C. § 321(g)(1)(C). The FDCA generally prohibits delivery of a new drug in interstate commerce absent an approved new drug application. *See* 21 U.S.C. § 355.[4] A new drug application must include adequate tests showing the drug product to be safe. *See* 21 U.S.C. § 355 (b), (d); *see also* 21 C.F.R. § 314. In addition, the FDCA prohibits delivery of "misbranded" drug products in interstate commerce. *See* 21 U.S.C. § 331. A drug

[4] In some cases, drug manufacturers may need to file and seek approval of a Biologics License Application or conform to OTC "monograph" requirements. (FAC ¶¶ 29-31.)

product will be deemed "misbranded" for a variety of reasons, including if it fails to disclose any material fact about the drug to consumers, if the labeling omits the established name or quantity of any active ingredient, or if it fails to warn about unsafe uses (among other things). *See* 21 U.S.C. § 352.[5]

The FDA explicitly states that its Center for Drug Evaluation and Research regulates certain "categories of biological products mostly produced by biotechnology methods, including: … *growth factors* …" (emphasis added).[6] According to the FAC, there is *no approved drug application for TNS® Products*, and these growth factor products are misbranded under the FDCA and Sherman FD&C. (FAC ¶¶ 6, 42-44, 85.) Neither the FDA nor the California Department of Public Health ("DPH") has determined TNS® Products (or the growth factors therein) to be safe; neither has approved TNS® Products for marketing or sale. (*Id.*) Instead, the sale of TNS® Products is prohibited by law. (*Id.*)

Furthermore, under the FDCA and Sherman FD&C, a "cosmetic" product will be deemed "misbranded" if the labeling is false or misleading in any particular. *See* 21 U.S.C. § 362; *see also* Cal. Health & Safety Code at §111730. Notably, any cosmetic product whose safety has not been adequately substantiated prior to marketing with safety tests covering each ingredient shall be deemed misbranded under the FDCA unless it conspicuously warns consumers that the product's safety has not been adequately determined. *See* 21 CFR §§ 740.1, 740.10. The TNS® Product labeling contains no such warning.

E. Safety Concerns Associated with the TNS® Growth Factor Mix

As a threshold matter, Defendants were required by law and public policy to conduct adequate safety tests of TNS® Products and each ingredient therein, or warn consumers that the safety of TNS® Products had not been determined. The FAC alleges that Defendants have not conducted controlled safety studies in accordance

[5] *See* parallel provisions of California's Sherman FD&C, i.e., Cal. Health & Safety Code §§ 109925(c), 111330, 111335, 111550, 111560. (FAC ¶¶ 32-34, 37.)

[6] *See* FDA 101: BIOLOGICAL PRODUCTS, at 2.

with federal and state regulations. (FAC ¶¶ 7, 60, 62-64, 69, 85.)[7] In assessing the safety of growth factors in skin creams, the DermNet New Zealand Trust explains: "Much remains unknown at this time, especially in terms of long-term risk or stability, when growth factors are used in cosmetics and applied to skin. Well-controlled clinical studies are lacking." (FAC ¶ 52.)[8]

In addition, the FAC pleads that TNS® Products (or the growth factors therein) pose genuine safety concerns including increased cancer risks. (FAC ¶ 5.) Growth factors have known carcinogenic potential because they literally cause cells to grow, and every growth factor has certain tumor types that secrete the specific growth factor. (FAC ¶ 50.) According to the FAC, substantial research addresses the links between growth factors – including those contained in TNS® – and cancer. (FAC ¶ 51.) An *example* is referenced in the FAC, namely, the "Finch article". The article discusses the facts that KGF may contribute to tumor growth in specific situations, it may cause tumors to metastasize, it may protect malignant cells, and/or it may foster secondary malignancies. (RJN, Ex. 1 at 812, 819.)

Plaintiff amply alleges that TNS® Products (or the growth factors therein) pose health risks. The FAC looks at two approved growth factor products (Regranex® and Kepivance®), the labeling of which provide prominent safety warnings about increased cancer risks. (FAC ¶¶ 55-58.) Regranex® contains a platelet-derived growth factor ("PDGF") found in studies to increase the risks of cancer. PDGF is associated with TNS®, either as a direct ingredient or because TNS® can induce the body to produce it. (*See* RJN, Ex. 2 at 356.) Kepivance®, a form of the "KGF-1" growth factor, was found to increase the growth of tumor cells. Admittedly, TNS® Products contain KGF-1. (FAC ¶ 51.)

[7] Defendants do not even disclose the name and quantity of each active ingredient in TNS®; the product labels merely refer to a "Human Fibroblast Conditioned Media". (FAC ¶ 24.)

[8] SkinMedica's own research in 2007 acknowledged that more controls on product quality and stability were needed and the effects of growth factors in conjunction with other procedures or products should be evaluated further. (RJN, Ex. 2 at 357.)

F. Defendants' Failure to Disclose the True Regulatory and Safety Status of TNS® Products

Plaintiff alleges that, in marketing and selling these expensive cosmeceuticals to consumers, Defendants fail to disclose the true regulatory and safety status of TNS® Products. Namely, Defendants omit the facts that: (i) TNS® Products are misbranded drug products being sold illegally without prior regulatory approval; (ii) safety for TNS® Products has not been adequately determined; and (iii) the TNS® growth factor mix poses genuine safety concerns. (FAC ¶ 7.) Defendants had a duty to disclose these facts based on the governing drug and cosmetic regulations and in light of Defendants' superior knowledge and concealment of the true facts. (FAC ¶¶ 59-66.)

G. Plaintiff's Claims in This Action

Plaintiff alleges that Defendants' conduct violates the Sherman FD&C (California's Health & Safety Code §§ 109875 *et seq.*) and the following consumer protection statutes: (i) California's Business & Professions Code §§ 17200, *et seq.* (the Unfair Competition Laws or "UCL"); (ii) California Civil Code §§ 1750, *et seq.* (the Consumers Legal Remedies Act or "CLRA"); (iii) California's Business & Professions Code §§ 17500, *et seq.* (the False Advertising Laws or "FAL"); and (iv) California Civil Code §§ 1709-1710 (Deceit). (FAC ¶¶ 8, 91-131.)

III. LEGAL STANDARDS

A. Motion to Dismiss Standards under Rules 8(a), 9(b), and 12(b)(6)

A motion to dismiss under Federal Rule of Civil Procedure 12(b)(6) tests the legal sufficiency of the claims asserted in the complaint. *See Ashcroft v. Iqbal*, 556 U.S. 662, 678-79, 129 S. Ct. 1937, 173 L. Ed. 2d 868 (2009).[9] Rule 12(b)(6) is read in conjunction with Federal Rule of Civil Procedure Rule 8(a), which requires a short and plain statement of the claim showing that the pleader is entitled to relief. While the Rule 8 pleading standard does not require detailed factual allegations, it does

[9] Internal citations and quotations omitted and emphasis in original unless otherwise indicated.

require more than mere legal conclusions. *Iqbal*, 556 U.S. at 678.

On a motion to dismiss, the district court accepts as true a plaintiff's well-pled factual allegations and construes all factual inferences in the light most favorable to the plaintiff. *Manzarek v. St. Paul Fire & Marine Ins. Co.*, 519 F.3d 1025, 1031 (9th Cir. 2008). Dismissal of a complaint for failure to state a claim is not proper where a plaintiff has alleged "enough facts to state a claim to relief that is plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570, 127 S. Ct. 1955, 167 L. Ed. 2d 929 (2007). "A claim has facial plausibility when the plaintiff pleads factual content that allows the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Iqbal*, 556 U.S. at 678.

To the extent applicable, Federal Rule of Civil Procedure 9(b) requires that allegations of fraud be "state[d] with particularity." However, "omissions" need not be pled with the same degree of specificity. *See Falk v. General Motors Corp.*, 496 F. Supp. 2d 1088, 1098-99 (N.D. Cal. 2007) (time, place, and content of omissions need not be pled with same specificity as affirmative misrepresentations); *see also Peel v. BrooksAmerica Mortg. Corp.*, 788 F. Supp. 2d 1149, 1159-60 (C.D. Cal. 2011). The purpose of Rule 9(b) is to require a plaintiff to be "specific enough to give defendants notice of the particular misconduct which is alleged to constitute the fraud charged so that they can defend against the charge and not just deny that they have done anything wrong." *Swartz v. KPMG LLP*, 476 F.3d 756, 764 (9th Cir. 2007).[10]

B. General Standards for the UCL, CLRA, FAL, and Civil Deceit

Under California Business & Professions Code §§ 17200, *et. seq.* (the Unfair Competition Law or "UCL"), any person or entity that has engaged, is engaging, or threatens to engage "in unfair competition may be enjoined in any court of competent jurisdiction." Cal. Bus. & Prof. Code §§ 17201, 17203. "Unfair competition" includes

[10] "[I]f particular averments of fraud are insufficiently pled under Rule 9(b), a district court should 'disregard' those averments, or 'strip' them from the claim. The court should then examine the allegations that remain to determine whether they state a claim." *Vess v. Ciba-Geigy Corp. USA*, 317 F.3d 1097, 1105 (9th Cir. 2003).

"any unlawful, unfair or fraudulent business act or practice and unfair, deceptive, untrue or misleading advertising." *Id.* at § 17200. The California Supreme Court construes "unfair competition" broadly. *See Cel–Tech Cmmc'ns, Inc. v. Los Angeles Cellular Tel. Co.*, 20 Cal. 4th 163, 180, 973 P.2d 527 (1999) ("Because Business and Professions Code section 17200 is written in the disjunctive, it establishes three varieties of unfair competition—acts or practices which are unlawful, or unfair, or fraudulent"). Here, Plaintiff alleges that the prohibited marketing and sale of misbranded TNS® Products was unlawful. Additionally or alternatively, the challenged acts and omissions were unfair and/or deceptive to a reasonable consumer.

The Consumers Legal Remedies Act, Cal. Civ. Code §§ 1750, *et seq.* (the "CLRA") makes illegal any "unfair methods of competition and unfair or deceptive acts or practices undertaken by any person in a transaction intended to result or which results in the sale or lease of goods or services to any consumer." Cal. Civ. Code § 1770(a). In particular, Section 1770(a)(2) prohibits "[m]isrepresenting the source, sponsorship, approval, or certification of goods or services;" Section 1770(a)(5) prohibits "[r]epresenting that goods or services have . . . characteristics, . . . uses, benefits, or quantities which they do not have . . .;" Section 1770(a)(7) prohibits "[r]epresenting that goods . . . are of a particular standard, quality, or grade . . . if they are of another." The CLRA is to be "liberally construed and applied to promote its underlying purposes, which are to protect consumers against unfair and deceptive business practices and to provide efficient and economical procedures to secure such protection." *Colgan v. Leatherman Tool Grp., Inc.*, 135 Cal. App. 4th 663, 680, 38 Cal. Rptr. 3d 36, 46 (2006). Plaintiff alleges that the challenged misbranding and omissions violate Section 1770(a), subparts (2), (5), and (7).

The False Advertising Law, California Business & Professions Code §§ 17500, *et. seq.* (the "FAL") broadly proscribes deceptive advertising in California. Section 17500 generally prohibits a company from making any untrue or misleading statement in advertising products, which reasonably should be known to be untrue or

misleading, or not to sell those products as advertised. The challenged misbranding and omissions constitute false advertising under the FAL.

Plaintiff also alleges that the challenged misbranding and omissions of material fact constitute Deceit under California Civil Code §§ 1709-1710. Section 1709 provides: "One who willfully deceives another with intent to induce him to alter his position to his injury or risk, is liable for any damage which he thereby suffers." Under Section 1710, Deceit includes: "[i] The suggestion, as a fact, of that which is not true, by one who does not believe it to be true; or [ii] the suppression of a fact, by one who is bound to disclose it, or who gives information of other facts which are likely to mislead for want of communication of that fact."

IV. ARGUMENT

A. Plaintiff Adequately Alleges that TNS® Products Qualify as "Drug" Products.

A "drug" includes any article "*intended to affect the structure or any function of the body of man.*" 21 U.S.C. § 321(g)(1)[C] (emphasis added). The vendor's "intent may be derived or inferred from labeling, promotional material, or any other relevant source." *United States v. Storage Spaces Designated Nos. "8" & "49"*, 777 F.2d 1363, 1366 (9th Cir. 1985). The FDCA is "given a liberal interpretation to effectuate its high purpose of protecting unwary consumers in vital matters of health." *United States v. Hohensee*, 243 F.2d 367, 370 (3rd Cir.1957) (*cert. denied*, 353 U.S. 976, 77 S.Ct. 1058, 1 L.Ed. 2d 1136 (1957)); *see also United States v. Livdahl*, 459 F. Supp. 2d 1255, 1260 (S.D. Fla. 2005) (finding allegations sufficiently alleged "that one of the 'intended uses' of [defendant's] product was the treatment of facial wrinkles, and that this intended use brings the product within the definitions of a 'drug' set forth in 21 U.S.C. § 321(g)(1)(C)").

"Some products, such as a skin cream, can be both a cosmetic and a drug under the FDCA. If a product is both, it must comply with the stricter requirements applicable to drugs." *Estée Lauder, Inc. v. FDA*, 727 F. Supp. 1, 2 (D.D.C. 1989); *see*

also United States v. An Article ... "Sudden Change", 409 F.2d 734, 739 (2d Cir. 1969) (skin cream qualified as drug product); *United States v. An Article ... "Line Away" ...*, 415 F.2d 369, 371-372 (3d Cir. 1969) (same).

As set forth in the FAC, Defendants intend for TNS® Products to have a physiological effect on the body, and in particular, to affect the structure or function of the skin. Through press releases, research publications, product guides, and labeling, Defendants promote the ability of these products to stimulate skin cell growth, slow the skin's aging process, reduce sun damage, increase collagen production, increase the skin's thickness, and regenerate and remodel the skin's structure. (FAC ¶¶ 40, 46; *see also* RJN, Ex. 2.) From the outset, SkinMedica has presented itself as a pharmaceutical company that markets physician-dispensed cosmeceuticals, including "Tissue Nutrient Solutions" products. (FAC ¶¶ 20, 23.)

Defendants promote "growth factors" as the key ingredients in TNS® Products (FAC ¶ 23), since growth factors stimulate cell growth – indeed the only reason to advertise the use of growth factors is to highlight their physiological effects. Importantly, the FDA publicizes: "The Center for Drug Evaluation and Research (CDER) within FDA regulates other categories of biological products mostly produced by biotechnology methods, including: . . . *growth factors (proteins that affect the growth of a cell)*."[11]

Equally important, SkinMedica's Product Guide advertises how: (i) growth factors work as proteins that "regulate cellular growth and the activity of skin cells;" (ii) a "*physiologically balanced*" mix of growth factors is needed in the skin "to maintain a healthy skin structure;" (iii) TNS® is "a combination of growth factors and other naturally occurring elements that are crucial to the regeneration of healthy skin;" (iv) TNS® is vital to the anti-aging process and works with the skin's "natural cellular restructuring process" to "reduce the appearance of fine lines and wrinkles, diminish age spots, and improve skin texture and elasticity;" and (v) SkinMedica further

[11] *See* FDA 101: BIOLOGICAL PRODUCTS, at 2 (emphasis added).

describes its flagship TNS® Product as the first and only "patented anti-aging treatment" using a combination of "growth factors clinically proven to improve" skin tone, texture, and elasticity. (FAC ¶ 25, Fig. 1, ¶ 40; *see also* RJN, Ex. 2.)

The marketing, product labeling and advertising for TNS® Products, and the supporting publications discussed above, objectively convey how Defendants intend for TNS® to have a physiological effect on the structure and/or function of the skin. The corresponding allegations in the FAC are not conclusory. To the contrary, the FAC puts Defendants on notice of how and why TNS® Products qualify as drug products.

Defendants repeatedly rely on *United States v. Kasz Enters.*, 855 F. Supp. 534, *amended*, 862 F. Supp. 717 (D.R.I. 1994), with regard to assessing a vendor's objective intent about its products. (Mem. of P. & A. in Supp. of Defs' Mot. to Dismis, June 23, 2014, ECF No. 20-1 ("MTD") at 7, 17.) *Kasz* helps to show how TNS® Products qualify as drugs. In *Kasz*, the court found that certain hair loss products ("Solutions 109") qualify as drug products "because they are represented to have a physiological effect on the body of man, namely, to cause hair growth and to prevent hair loss." 855 F. Supp. at 540. The Ninth Circuit reached a similar conclusion in *FTC. v. Pantron I Corp.*, 33 F.3d 1088, 1104 (9th Cir. 1994) ("We see no error in the district court's conclusion that the Helsinki Formula is intended to affect the bodily function of hair growth").[12] Similarly, TNS® Products qualify as drug products because Defendants represent their products to have a physiological effect on the human body by promoting skin cell growth, reducing wrinkles, sun damage and the effects of aging, promoting collagen production, increasing the skin's thickness and elasticity, and otherwise regenerating or remodeling the skin's structure.

Next, Defendants rely on *Dole Food Co.*[13] and *Welch Foods, Inc.*[14] to suggest

[12] Moreover, in *Pantron I Corp.*, the Ninth Circuit had no trouble distinguishing a case in which a vendor advertises "only that [a lotion] would cause *a temporary, superficial change* in the user's appearance" for *a matter of hours*. *Id.* (emphasis added).

[13] *Brazil v. Dole Food Co.*, 935 F. Supp. 2d 947, 964 (N.D. Cal. 2013).

that the FAC fails to specify how TNS® Products qualify as drugs. (MTD at 18.) These cases, however, are inapposite. They concern food labeling claims, and articles of "food" are expressly excluded from the definition of "drugs"). The cases have no bearing on whether the FAC adequately alleges that TNS® Products qualify as drug products (which, plainly, they do).

Defendants also contend that there are other skin care products on the market containing human growth factors, which are not addressed in the FAC. (MTD at 19.) No doubt, other companies could be selling unapproved skin creams that qualify as drug products. This in no way undercuts the fact that TNS® Products are drug products. Defendants further contend that the FDA has not specifically announced that TNS® Products are "drugs" or that they are unlawfully sold. (*Id.*) In truth: "The fact is that many drugs are in widespread use without FDA approval as 'new drugs.' The FDA is well aware of the marketing of unapproved drugs. . . . The FDA cannot, as a practical matter, use its enforcement powers to remove all unapproved drugs from the market place at once." *Pedinol Pharmacal, Inc. v. Rising Pharm., Inc.*, 512 F. Supp. 2d 137, 140 (E.D.N.Y. 2007) (finding no question that skin cream for dry skin, containing lactic acid as an active ingredient, qualified as a drug product).

Finally, Defendants argue that TNS® Products are "not intended to be drug products." Defendants misconstrue the relevant "intent" under the FDCA and Sherman FD&C. What matters in this context are the "intended *uses or effects* of the product", i.e., whether the products are intended to affect the structure or any function of the body. *See Kasz*, 855 F. Supp. at 539 (emphasis added); *see also United States v. An Article… "Line Away, Temp. Wrinkle Smoother, Coty"*, 284 F. Supp. 107, 111 (D. Del. 1968) *aff'd*, 415 F.2d 369 (3d Cir. 1969) ("Nor is it of significance that Line Away is described as a cosmetic on some of the labels, selling literature or advertisements. The essential question is whether the product falls within the

[14] *Park v. Welch Foods, Inc.*, No. 5:12-CV-06449-PSG, 2013 WL 5405318 (N.D. Cal. Sept. 26, 2013).

definition of a drug in the Act"). Therefore, it does not help Defendants to disclaim that its products are intended "to be drug products" given that – in light of the intended uses and effects on the skin – TNS® Products fall well within the statutory definition of a drug.

B. Plaintiff Sufficiently Alleges that the Omitted Facts about the Regulatory Status and Safety Status of TNS® Products Are True.

1. *TNS® Products are unapproved drugs being sold to consumers illegally.*

As set forth in Section IV(A) above, the FAC pleads considerable facts showing that TNS® Products qualify as drug products. There is no dispute, however, that Defendants market and sell TNS® Products without FDA approval and without complying with the regulatory scheme for drug products. Simply put, then, the FAC sufficiently alleges that TNS® Products are unapproved and misbranded drugs being sold to consumers illegally.

2. *Defendants failed to adequately determine that TNS® Products are safe, which Defendants were required to do before marketing and selling such products to consumers.*

Through the FDA approval process, a vendor must affirmatively show that a drug product is safe. *See*, *e.g.*, 21 U.S.C. § 355 (b), (d) (applicant's investigation must include adequate safety tests showing that the drug product is safe).[15] Without pursuing and securing a new drug application (FAC ¶ 43), Defendants bypassed the federal and state drug safety review entirely. Defendants do not even disclose the name and quantity of each active ingredient in TNS®. This failure alone constitutes misbranding. (FAC ¶ 24.) In any event, Defendants offer no studies to substantiate the safety of their so-called "Human Fibroblast Conditioned Media" – either as a whole or with respect to the many biological ingredients contained therein. Accordingly, the FAC sufficiently alleges that Defendants failed to conduct adequate

[15] *See also* 21 C.F.R. § 314 (providing for a thorough review of drugs (i) to facilitate approval of drugs shown to be safe and (ii) to ensure the disapproval of drugs not shown to be safe); Cal. Health & Safety Code §§ 111550, 111560 (requiring new drug applications to be supported by adequate safety tests).

safety studies for TNS® Products as required by law. (FAC ¶¶ 7, 52, 54, 62.)[16]

In their Motion, Defendants claim that SkinMedica has "safely" sold these products to thousands of consumers across the country for over a decade. (MTD at 1, 15.) In truth, the safety of TNS® Products cannot be substantiated based merely on Defendants' purported history of sales without major incident reports. Adequate *safety testing* is mandatory. *See* 21 U.S.C. § 355 (d) (drug safety tests required); *see also* FDA Cosmetic Labeling Manual, 1991 WL 11250880, at *17 (FDA Oct. 1, 1991) (In order for safety of a cosmetic to be adequately substantiated, qualified scientific experts must determine safety from *toxicological and other test data*). Defendants do *not* show that, in fact, they performed adequate safety tests. They do *not* show that TNS® Product consumers were evaluated for malignancies or increased health risks over the past decade. At most, Defendants suggest that consumers chose not to spontaneously report major incidents to Defendants, which establishes little if anything. Without TNS® Product warnings on the label, consumers who did experience health problems would have little reason to report them to Defendants (except perhaps for immediate skin reactions).

Defendants argue that *advertising claims* based on "*lack of substantiation*" are not cognizable under the California consumer protection laws. (MTD at 15.) The argument is misplaced. The "lack of substantiation" cases – which spring from *National Council Against Health Fraud v. King Bio Pharm., Inc.*, 107 Cal. App. 4th 1336, 1344-45 (2003) – deal with a different situation than the one presented here.

In *King Bio*, the California Court of Appeal considered a claim that a homeopathic remedy was not shown to be effective as advertised. The court addressed the fact that Business & Professions Code Section 17508 permits the

[16] TNS® Products are cosmetics *and drugs* for the reasons discussed above. Furthermore, a cosmetics vendor must warn consumers that "safety for [the] product has not been determined" unless *each ingredient* has been substantiated for safety with adequate test data. *See* 21 CFR §§ 740.1, 740.10; *see also* Cal. Health & Safety Code §§ 110290, 111730. Safety for TNS® Products (and each ingredient) has never been determined with adequate tests. Yet, Defendants do not warn consumers of this.

Attorney General (but not private persons) to require an advertiser to substantiate an advertising claim. *See King Bio*, at 1343. The court held that private plaintiffs have the burden of producing evidence that an advertising claim is false or misleading. In the process, the court distinguished claims based on regulatory violations like the ones raised here. The court in *King Bio* observed that:

> The FDA permits homeopathic remedies included in the Homeopathic Pharmacopoeia to be marketed. King Bio's products are included in the Homeopathic Pharmacopoeia and otherwise comply with FDA regulations. Thus, prior to the marketing of a product by King Bio, the general efficacy and safety of the remedy has been substantiated to the extent required by federal law. Public policy would not be furthered under these circumstances by requiring King Bio to substantiate its advertising claims as to general efficacy every time a private plaintiff brings a false advertising action. *Id.* at 1348.

The case at hand is quite different. Here, by contrast: (i) the FDA does *not* permit new drugs to be marketed without prior submission of adequate safety tests; (ii) TNS® Products do *not* comply with the FDA regulations and parallel state law provisions for drugs and cosmetics; (iii) prior to marketing, Defendants did *not* conduct adequate safety tests of TNS® Products to the extent required by state and federal law, and of course (iv) Defendants did *not* secure regulatory approvals. In light of the foregoing, Plaintiff can and does sufficiently allege that Defendants failed to adequately determine the safety of TNS® Products as required by law.[17]

Stated another way, Defendants were required by law to show that TNS®

[17] Significantly, not one of Defendants' "lack of substantiation" cases deals with the laws requiring vendors to show that their drug products are safe (or in the case of cosmetics, to warn consumers whenever the safety of the products has not been determined through an examination of adequate test data).

Products were safe before marketing and selling those products to consumers – their failure to do so is both demonstrable and actionable here.

3. *The TNS® growth factor mix raises genuine safety conerns.*

The FAC sufficiently alleges additional facts showing that TNS® raises genuine safety concerns (including potential cancer risks).

First, at the most basic level, the FAC alleges that TNS can cause adverse reactions. According to the FAC, Defendants have ignored consumer reports of adverse reactions relating to TNS® Products. (FAC ¶ 63.)[18] In addition, the scientific literature has observed adverse reactions (such as allergies, eye issues, and rashes) to growth factors associated with TNS®. (FAC ¶ 50.) The TNS Product labeling, however, does not warn of any adverse reactions. (FAC ¶ 54.) In short, the FAC adequately alleges facts showing that TNS® Products may cause adverse reactions, which are known to Defendants but not disclosed to consumers.

Second, the FAC alleges facts showing that TNS® has carcinogenic potential because it can cause cells to grow, and every growth factor has certain tumor types that secrete the specific growth factor. (FAC ¶ 50.) Indeed, Defendants do not dispute that TNS® stimulates cell growth. (*See*, *e.g.*, RJN, Ex. 2.) Common sense leads one to ask: "What stops TNS® from stimulating cancer cells?"

Third, the Regranex® and Kepivance® studies illustrate cancer-related risks associated with one or more of the ingredients in TNS®. (FAC ¶¶ 55-58.) Defendants argue that Regranex® and Kepivance® are drugs that differ from TNS® Products, for example, because they are not applied topically to intact skin and do not have a balanced mix of 110 growth factors. (MTD at 9.) Drug and cosmetic vendors, however, must substantiate that *each ingredient* is safe (not just the product as a whole). The growth factors associated with Regranex® and Kepivance® (KGF-1, PDGF) have been shown to pose cancer-related risks. The same growth factors are

[18] Defendants assert that Plaintiff fails to point to a specific incident of an adverse reaction. (MTD at 12.) But, this is a tongue-in-cheek observation. Defendants do not (and cannot) say that they are unaware of adverse reaction reports.

contained in TNS® and could stimulate such growth factors in the body. Defendants offer no evidence showing that these risks dissipate once the growth factors are incorporated into TNS® and applied topically to the skin.

Defendants emphasize that TNS® Products contain a physiologically-balanced mix of 110 growth factors and other types of proteins, rather than just 1 or 2 growth factors. Yet, this only invites more serious health concerns. Exactly which other ingredients are found in TNS®, in what quantities, and how can Defendants say those ingredients are safe without controlled safety testing of *each* ingredient *and* the TNS® Products as a whole?[19]

Fourth, the scientific literature also reflects that growth factors (including those associated with TNS®) can pose cancer-related risks. (FAC ¶ 51.) The *Finch article* referenced in the FAC is but one example. Defendants note a few observations from the 2006 *Finch article* addressing a lack of evidence that KGF generally promotes the growth of tumors,[20] and how KGF may have beneficial health effects. (MTD at 4.) Defendants simply disregard the potential cancer risks actually discussed in the article, including the facts that KGF may contribute to tumor growth in specific situations, it may cause metastasis, and it may foster malignancies. (RJN, Ex. 1 at 812, 819.)

Defendants cite to *Corral* as an example of safety-related allegations that were found to be deficient,[21] but the allegations in *Corral* dealt with crib bumpers, not drugs or cosmetics. There is no regulatory framework requiring vendors to substantiate that a crib bumper is safe. Furthermore, the plaintiff in *Corral* did not allege a factual link between the defendant's crib bumper and any risk of harm. Here, by contrast, there is

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[19] Neither *Otto v. Abbott Labs., Inc..*, No. CV 12-1411-SVW (DTB), 2013 U.S. Dist. Lexis 53287 (C.D. Cal. Mar. 15, 2013) nor *Eckler v. Wal-Mart Stores, Inc.*, No. 12-CV-727-LAB-MDD, 2012 WL 5382218 (S.D. Cal. Nov. 1, 2012) deals with drugs or cosmetics, and neither case intimates that only a combination of ingredients could pose safety concerns, as Defendants wrongly suggest.

[20] The more recent Regranex® study, however, now provides such evidence.

[21] *Corral v. Carter's Inc.*, No. 1:13-CV-0262 AWI SKO, 2014 WL 197782 (E.D. Cal. Jan. 16, 2014).

a regulatory framework that requires vendors of drugs and cosmetics to substantiate the safety of their products through adequate testing or warn consumers that safety of the products has not been determined. Plaintiff also alleges a factual link between one or more of the ingredients found in Defendants' TNS® mix and increased cancer risks.

For the foregoing reasons, TNS® raises genuine safety concerns.

C. Plaintiff Adequately Alleges a Duty to Disclose and Scienter.

Defendants maintain that there is no duty to disclose the alleged facts about the regulatory and safety status of TNS® Products. This is because, in Defendants' view, no regulatory or safety issues exist in the first place. For reasons discussed in Sections IV(A) and (B) above, Plaintiff adequately alleges that TNS® Products are unapproved and misbranded drugs, Defendants have not shown TNS® to be safe as required by law, and TNS® otherwise poses genuine safety concerns. Consequently, Defendants had a duty to disclose these facts consistent with the FDCA, Sherman FD&C, and California's consumer protection laws. Moreover, the FAC sufficiently alleges a duty to disclose and scienter arising from Defendants' superior knowledge and concealment of such facts. (FAC ¶¶ 59-66.)[22]

D. Plaintiff Adequately Alleges Her Claims Against Defendant Allergan as a Parent Company that Cross-Promotes the TNS® Products.

1. *The FAC sufficiently differentiates between SkinMedica and Allergan.*

Under Rule 9(b), a plaintiff must identify the role of each defendant in the alleged misconduct. *See Swartz*, 476 F.3d at 765. On the other hand, a plaintiff need not break out and repeat all allegations separately for each defendant. *See Swartz*, 476 F.3d at 765; *see also Williams v. Wells Fargo Bank N.A.*, No. 11-21233-CIV, 2011 WL 4901346, at *12 (S.D. Fla. Oct. 14, 2011) ("[W]hen multiple defendants are named in a complaint, the allegations can and usually are to be read in such a way that each defendant is having the allegation made about him individually"). In this case,

[22] Under Rule 9(b), knowledge and intent may be alleged generally. *See* Fed. R. Civ. P. Rule 9(b).

the FAC contains extensive allegations as to the marketing and sale of misbranded TNS® Products, and the corresponding failure to disclose material facts about the regulatory/safety status of TNS® Products. All such allegations directly and unambiguously apply to Defendant SkinMedica, Inc. in the first instance.

Beyond this, the FAC also alleges that Defendant Allergan, Inc. acquired SkinMedica on or about December 19, 2012. (FAC ¶ 12.) SkinMedica is now "an Allergan Company". (FAC ¶ 2.) Since the acquisition, Allergan has held out the SkinMedica TNS® Products to be "Allergan products" too, and Allergan has represented to consumers that all safety concerns associated with these products are described on package inserts that accompany its products. (FAC ¶¶ 12, 49.) In sum, the FAC adequately identifies the role of each Defendant in the alleged misconduct.

2. *The FAC sufficiently alleges that Allergan holds out TNS® Products to be Allergan products.*

According to Defendants, TNS® Products are not *Allergan* products. (MTD at 21.) The FAC adequately alleges otherwise. Namely, while SkinMedica certainly markets and sells TNS® Products, the same products are *cross-promoted as Allergan products*. (FAC ¶¶ 12, 49.) In this regard, Allergan publishes "a list of *Allergan products*" for which it claims that "all safety concerns regarding *our products* are described on the package inserts that accompany them."[23] TNS® Products are included on the Allergan product list. Based upon the cross-promotion of TNS® Products by SkinMedica *and Allergan,* Plaintiff adequately alleges claims against both Defendants in this action.

E. Plaintiff Sufficiently Pleads a Claim for Punitive Damages.

A consumer who suffers damage as a result of the use of a practice proscribed under the CLRA may recover punitive damages. Cal. Civ. Code § 1780(a)(4). In addition, anyone who willfully deceives another person may be liable for punitive

[23] Letter from Sulaiman Hamidi, Allergan Manager of Health & Safety, to Allergan Customers, May 2014 (emphasis added), *available on Allergan, Inc.'s website at*: http://www.allergan.com/assets/pdf/msds/ehs-material_safety_data_sheet_letter.pdf.

damages. Cal. Civ. Code §§ 1709, 1710, 3294(a). In this case, Plaintiff adequately pleads that she suffered damages as a result of Defendants' CLRA violations and willful deceit. (FAC ¶¶ 101-112, 123-131). Furthermore, Plaintiff alleges that Defendants suppressed material facts with the intent to deprive consumers of money. (FAC ¶ 129.) These allegations adequately support a prayer for punitive damages.

Defendants argue that the FAC fails to plead how *"officers, directors, or managing agents"* for Defendants consciously disregarded, authorized, or ratified the alleged fraud. They mistakenly rely on pleading rules in Cal. Civ. Code § 3294(b), which explicitly and exclusively apply to claims by *employees* against *employers*.[24] Predictably, Defendants sole authority – *White v. Ultramar, Inc.*, 21 Cal. 4th 563 (1999) – is a wrongful termination case. Here, Plaintiff does not bring an action against her employer, and thus, Civil Code § 3294(b) is inapposite. In other words, Plaintiff need not plead that an "officer, director, or managing agent" for each Defendant consciously disregarded, authorized, or ratified the challenged practices.

F. Plaintiff Has Standing to Seek Injunctive Relief.

To demonstrate Article III standing, a plaintiff must establish that: (1) they have suffered an "injury in fact," (2) there is a "causal connection between the injury and the conduct complained of," and (3) it is "likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560-61, 112 S.Ct. 2130, 119 L.Ed. 2d 351 (1992). For injunctive relief, a plaintiff must show a threat of repeated injury. *See Bates v. United Parcel Serv., Inc.*, 511 F.3d 974, 985 (9th Cir. 2007).

Defendants do not dispute that Plaintiff alleges a concrete injury-in-fact caused by the challenged conduct. Instead, Defendants contend that there is no threat of repeated injury now that Plaintiff is aware of the true facts about TNS® Products. (MTD at 23-24.) While past wrongs standing alone do not show a threat of future

[24] "An *employer* shall not be liable for damages pursuant to subdivision (a), based upon acts of an *employee* of the *employer*. . . ." *Id.* (emphasis added); see also *White v. Ultramar, Inc.*, 21 Cal. 4th 563, 566-67 (1999).

injury, "past wrongs are evidence bearing on whether there is a real and immediate threat of repeated injury[.]" *O'Shea v. Littleton*, 414 U.S. 488, 496, 94 S.Ct. 669, 38 L.Ed. 2d 674 (1974). To be sure, past sales *combined with ongoing marketing of misbranded products* should suffice to show a threat of repeated injury for purposes of Article III standing:

> If the Court were to construe Article III standing for FAL and UCL claims as narrowly as the Defendant advocates, federal courts would be precluded from enjoining false advertising under California consumer protection laws because a plaintiff who had been injured would always be deemed to avoid the cause of the injury thereafter ("once bitten, twice shy") and would never have Article III standing. While Plaintiffs may not purchase the same [] products as they purchased during the class period, because they are now aware of the true content of the products, to prevent them from bringing suit on behalf of a class in federal court would surely thwart the objective of California's consumer protection laws. . . . Defendant has not presented evidence or even alleged that it has removed its allegedly misleading advertising from its products. With such advertising remaining on supermarket shelves, Plaintiffs, as representatives of a class, should be entitled to pursue injunctive relief on behalf of all consumers in order to protect consumers from Defendant's alleged false advertising.

Henderson v. Gruma Corp., No. CV 10-04173 AHM AJWX, 2011 WL 1362188, at *7-8 (C.D. Cal. Apr. 11, 2011); *see also Koehler v. Litehouse, Inc.*, No. CV 12-04055 SI, 2012 WL 6217635, at *6 (N.D. Cal. Dec. 13, 2012) ("The Court

agrees with *Henderson.* To do otherwise would eviscerate the intent of the California legislature in creating consumer protection statutes because it would effectively bar any consumer who avoids the offending product from seeking injunctive relief"); *Fortyune v. American Multi–Cinema, Inc.*, No. CV 10–5551, 2002 WL 32985838, at *7 (C.D. Cal. Oct. 22, 2002).

In this case, Plaintiff alleges that she purchased an unapproved and misbranded drug product that was manufactured and unlawfully marketed by Defendants. Since the challenged conduct is ongoing, Defendants can continue to subject Plaintiff and the putative class to similarly unlawful, unfair, and deceptive marketing in the future. At the motion to dismiss stage, Plaintiff's prior purchase combined with Defendants' ongoing marketing sufficiently shows a threat of repeated injury.

V. CONCLUSION

For the foregoing reasons, Defendants' Motion to Dismiss the First Amended Class Action Complaint should be denied in its entirety.

DATED: July 8, 2014

Respectfully submitted,

HAGENS BERMAN SOBOL SHAPIRO LLP

By: /s/ Lee M. Gordon
Lee M. Gordon

lee@hbsslaw.com
301 North Lake Avenue, Suite 203
Pasadena, CA 91101
Telephone: (213) 330-7150
Email: lee@hbsslaw.com

Steve W. Berman (admitted *pro hac vice*)
steve@hbsslaw.com
HAGENS BERMAN SOBOL SHAPIRO LLP
1918 8th Avenue, Suite 3300
Seattle, WA 98101
Telephone: (206) 623-7292
Email: steve@hbsslaw.com

Attorneys for Plaintiff Josette Ruhnke and the Proposed Class

CERTIFICATE OF SERVICE

I hereby certify that on July 8, 2014, I electronically filed the foregoing document using the CM/ECF system which will send notification of such filing to the e-mail addresses registered in the CM/ECF system, as denoted on the Electronic Mail Notice List, and I hereby certify that I have caused to be mailed a paper copy of the foregoing document via the United States Postal Service to the non-CM/ECF participants indicated on the Manual Notice List generated by the CM/ECF system.

/s/ Andy Katz
ANDY KATZ